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RICHARD W. WIEKING
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THAD A. DAVIS (CSB # 220503)
Thad.Davis@ropesgray.com
JOSHUA VAN HOVEN (CSB # 262815)
Joshua.vanhoven@ropesgray.com
ROPES & GRAY LLP
1900 University Avenue, 6th Floor
East Palo Alto, CA 94303-2284
Phone: (650) 617-4000
Facsimile: (650) 617-4090

PETER M. BRODY
Peter.Brody@ropesgray.com
ROPES & GRAY LLP
700 12th Street, NW, Suite 900
Washington, DC 20005-3948
Telephone: (202) 508-4612
Facsimile: (202) 383-7777

Attorneys for Plaintiff
TRIA BEAUTY, INC.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CV10- 5053 HRL

TRIA BEAUTY, INC.

Plaintiff,

vs.

OREGON AESTHETIC TECHNOLOGIES, INC.,

Defendant

Case No.

COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES FOR: VIOLATION OF § 43(a) OF THE LANHAM ACT; VIOLATION OF CAL. BUS. & PROF. CODE § 17500; AND VIOLATION OF CAL. BUS. & PROF. CODE § 17200

JURY TRIAL DEMANDED

1. Plaintiff TRIA Beauty, Inc. ("TRIA" or "Plaintiff"), by its attorneys, Ropes & Gray LLP, files this Complaint against defendant Oregon Aesthetic Technologies, Inc. ("OAT" or "Defendant") to obtain relief from false and misleading advertising and other unfair competitive practices by OAT that are designed to, and do, induce customers to purchase OAT's purported acne-treatment device and are thereby causing TRIA substantial injury in the market for such products. In support of its claims for relief, TRIA avers particularly as follows:

PARTIES

2. Plaintiff is a Delaware corporation with its principal place of business in Dublin, California.

3. Upon information and belief, Defendant is an Oregon corporation with its principal place of business in Portland, Oregon.

JURISDICTION

4. This Court has original subject matter jurisdiction over this action pursuant to 15 U.S.C. § 1121. This Court has related claim jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

5. This Court has personal jurisdiction over Defendants because Defendants have established minimum contacts with the State of California by purposefully availing themselves of, and doing business in, the State of California through extensive sales in that state and advertising there in various media, including the Internet.

VENUE

6. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the false and misleading advertising and unfair competition complained of in this complaint has occurred and is occurring in this judicial district, and because TRIA and the public have suffered and continue to suffer injury in this judicial district as a result of the matters complained of herein.

FACTUAL BACKGROUND

The TRIA System

7. Plaintiff designs, manufactures, markets, and sells the TRIA Skin Clarifying System, an over-the-counter ("OTC") product for the treatment and prevention of acne ("TRIA System"). At the heart of the TRIA System is the Clarifying Blue Light, a medical device that delivers effective blue-light phototherapy in an OTC form. Blue-light phototherapy has been used by dermatologists in their offices to treat acne since 2002, because it clears acne without the negative side effects of topical or systemic drug alternatives by killing the bacteria in the skin that is one of acne's principal causes. The TRIA Clarifying Blue Light incorporates this same technology in an OTC device. The TRIA System also includes the Clarifying Foam Cleanser, which cleans, exfoliates, and prepares the skin for treatment by removing makeup and sunscreen, and the Rebuilding Complex, a post-treatment lotion with anti-acne and anti-oxidant properties designed to complement the blue light-treatment.

8. The Food and Drug Administration ("FDA") regulates the advertising and distribution of all "devices" that fall within the definition set forth in Section 201(h) of the Federal Food, Drug and Cosmetic Act ("FDC Act"), including any "instrument, apparatus, implement, machine, contrivance" which is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(h). With certain exceptions not relevant here, a medical device may not be introduced into interstate commerce without approval by the FDA of a premarket application or clearance by FDA of a premarket notification under Section 510(k) of the FDC Act. In a Section 510(k) notification, a person proposing to distribute a device in interstate commerce must demonstrate that its device is "substantially equivalent" to a previously legally marketed device, referred to as a "predicate device." The device may not be legally marketed unless and until FDA issues an order declaring the device that is the subject of the Section 510(k) notification to be substantially equivalent to the predicate identified in the submission. To establish substantial equivalence, the Section 510(k) notification must, among other things, demonstrate to FDA's satisfaction that any technological differences between the new device and the predicate device do not render the new device less safe or effective than the predicate device. The evidence to make such a showing may include, as FDA deems necessary, human clinical testing or other appropriate scientific data. 21 U.S.C. § 360c(i)(1).

9. Pursuant to its jurisdiction to regulate medical devices, the FDA classifies blue-light phototherapy devices for the treatment of acne as Class II medical devices, under FDA Product Code "GEX" or "OLP," and requires premarket clearance of each specific device under Section 510(k) before permitting such device to be introduced into, and advertised in, interstate commerce.

10. In April 2006, the FDA granted Section 510(k) clearance for a TRIA blue-light phototherapy device as a prescription device for acne treatment, for use under the supervision of a practitioner licensed by state law to direct the use of such device. *See* 21 C.F.R. § 801.109. In January 2010, the FDA granted Section 510(k) clearance for the TRIA Clarifying Blue Light as an OTC device for the treatment of acne, based on clinical and usability testing demonstrating the safety and effectiveness of that product for use in the home environment.

The OAT Device

11. Defendant OAT markets and sells a product called the "ANSR:BEAM" as an OTC phototherapy device for the treatment of acne. The ANSR:BEAM, however, has not been cleared by FDA for introduction into, or advertisement in, interstate commerce.

12. OAT distributes the ANSR:BEAM nationally through its Internet website at http://ansr.com. This website permits consumers located in any state, including California, to make direct purchases of the ANSR:BEAM.

13. OAT also distributes the ANSR:BEAM nationally through leading third-party on-line resellers of skin-care products including amazon.com, drugstore.com, skinstore.com, and dermadoctor.com, and through "bricks and mortar" retailers, including over 40 stores located in California, in this District and in other Districts. *See* http://ansr.com/locator. These resellers permit consumers located in any state, including California, to make direct purchases of the ANSR:BEAM.

OAT's False And Misleading Advertising Claims

14. OAT makes a number of claims stating or implying that the ANSR:BEAM has been clinically tested and proven to be safe and effective in treating acne, including the following:

- "The ANSR: BEAM utilizes safe, non-invasive, clinically proven light therapy (or phototherapy) technology—a favorite of dermatologists worldwide." http://www.ansr.com/acne_how_it_works.html.

- "This 100% guaranteed treatment uses the most modern proven scientific method available to the general public." http://www.acneansr.com/does-ansr-acne-treatment-work.php.
- "The light therapy technology that is used by the ANSR: Light Beam has been tested and proven by dermatologists to be effective for most acne patients." http://www.acneansr.com/does-ansr-acne-treatment-work.php.

OAT cites and summarizes a number of peer-reviewed clinical studies in support of its claim that the ANSR:BEAM is "clinically proven" to be safe and effective. http://www.ansr.com/science_research.html.

15. These claims are all false and misleading: as OAT has confirmed in recent correspondence with TRIA, the ANSR-BEAM has not been the subject of any clinical trials, at least none that has established its safety or effectiveness in treating acne. The peer-reviewed clinical studies cited by OAT were not studies of the ANSR:BEAM, but were studies of other blue-light phototherapy devices made by other manufacturers. While the safety and effectiveness of some LED blue-light-emitting devices (including TRIA's) certainly has been clinically proven in the studies cited by OAT, the mere fact that the ANSR-BEAM emits a form of LED blue light is an insufficient basis to claim that these studies "clinically prove" the safety and effectiveness of the ANSR:BEAM in particular. Indeed, if all LED blue-light phototherapy devices were equally safe and effective without regard to their particular physical properties (including, for example, their structure, configuration, functional attributes, and safety features) or their recommended method of use (including specific instructions on application times, location of use on the body, manner of application, appropriateness for use on various skin types, and safety warnings and precautions), FDA presumably would not require clearance of individual devices.

16. In its advertising, OAT also asserts that "The ANSR: BEAM has replicated the specific light wave frequencies of clinical treatments and developed a low-powered, safe, handheld, phototherapy unit, safe for daily use." http://ansr.com/science/red-light-blue-light. TRIA believes this claim, too, is false. Although OAT does not specify the frequency at which its device operates, TRIA has measured it in the laboratory at 674 terahertz, which equates to a wavelength of 445 nm.

By contrast, all of the studies cited by OAT involved blue-light phototherapy devices operating at a wavelength of 415 nm, which is also the case with the TRIA device and, to TRIA's knowledge, all other FDA-cleared LED phototherapy devices. That wavelength has been used by these devices because scientists long ago established its effectiveness in killing acne-causing bacteria. To TRIA's knowledge, there are no published studies, and certainly OAT cites none, indicating that LED blue-light phototherapy devices operating at a wavelength of 445 nm are effective in treating acne. Furthermore, even if the ANSR:BEAM did operate at the same wavelength as the blue-light LED devices proven to be effective in treating acne, numerous other optical and usage properties of the device also would have to be equivalent for the device to actually be effective as a treatment, including the power density, energy density, and treatment regimen. There is no evidence of such equivalence.

17. In light of these facts, TRIA believes that all of OAT's effectiveness claims for the ANSR:BEAM are false and misleading, even those that do not explicitly include an assertion that such effectiveness has been clinically tested and proven, including such claims as the following:

- "The BEAM kills acne causing bacteria and stimulates collagen deep below the skin's surface to control acne breakouts and improve overall skin texture and tone." http://ansr.com/acne/how-it-works.
- "The ANSR: BEAM produces narrow, light wave spectrums created by special, high-intensity Light-Emitting Diodes (LEDs) that are absorbed by skin cells. This light therapy is converted into chemical energy, which initiates a cascade of positive events at the cellular level." *Id.*
- "The ANSR: BLUE light waves are precise wavelengths of light energy selectively delivered to the targeted area beneath the skin to safely kill bacteria without causing dryness, redness or pain associated with most acne treatments." *Id.*
- "ANSR is the most advanced acne treatment that is guaranteed and it's available now!" http://www.acneansr.com/does-ansr-acne-treatment-work.php

18. Finally, OAT's extensive use in its advertising of such words and phrases as "clinically tested and proven," "scientific," "most advanced," and "replicated the specific light wave frequencies" and "precise wavelengths," coupled with its explicit and implicit comparisons to other blue-light phototherapy devices that are FDA cleared as safe and effective in treating acne, mislead an appreciable percentage of consumers into assuming that the ANSR:BEAM also has been determined by FDA to be safe and effective in treating acne, when FDA has made no such determination.

FIRST CLAIM FOR RELIEF

FEDERAL UNFAIR COMPETITION

[Lanham Act § 43(a), 15 U.S.C. § 1125(a)]

19. Plaintiff incorporates and realleges each of the averments of the previous paragraphs.

20. The above-described advertising claims made by Defendant either deceived or had the capacity to deceive a substantial segment of potential consumers for aesthetic hair removal products.

21. Defendant's deception was and is material, in that it was and is likely to influence a consumer's purchasing decisions.

22. Defendant has caused their false statements to enter interstate commerce.

23. Defendant's advertising claims, as alleged above, violate 15 U.S.C. Section 1125(a) and have caused and/or are likely to cause damage to TRIA and the public in an amount to be determined at trial, and, unless restrained, will further damage TRIA and the public.

24. In making and disseminating the above-described materially false and misleading advertising claims, Defendant knew, or by exercise of reasonable care should have known, that the claims were untrue and/or misleading and likely to deceive the public. Accordingly, the actions of Defendant were willful, and this is an exceptional case justifying an award of reasonable attorneys' fees.

SECOND CLAIM FOR RELIEF

CALIFORNIA FALSE ADVERTISING

[Cal. Bus. & Prof. Code § 17500]

25. Plaintiff incorporates and realleges each of the averments of the previous paragraphs.

26. Defendant's advertising, as alleged above, contains statements that are untrue or misleading. Defendant knows or should have known by exercise of reasonable care that the statements were untrue or misleading.

27. Defendant's advertising violates Section 17500 of the California Business and Professions Code. Plaintiff TRIA has suffered injury in fact and has lost money or property as a result of such unfair competition, causing damage to TRIA in an amount to be determined at trial, and, unless restrained, will further damage TRIA.

THIRD CLAIM FOR RELIEF

CALIFORNIA UNFAIR COMPETITION

[Cal. Bus. & Prof. Code § 17200 *et seq.*]

28. Plaintiff incorporates and realleges each of the averments of the previous paragraphs.

29. Defendant's advertising, as alleged above, constitutes unlawful, unfair and/or fraudulent conduct in violation of Section 17200 of the California Business and Professions Code. TRIA has suffered injury in fact and has lost money or property as a result of such unfair competition, causing damage to TRIA in an amount to be determined at trial, and, unless restrained, will further damage TRIA.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff seeks judgment as follows:

On the First Claim for Relief

1. For preliminary and permanent injunctions:

a. Enjoining and restraining Defendant and its agents, servants and employees from publishing or publicly disseminating any statement, either directly or indirectly, concerning the nature, characteristics and qualities of the ANSR:BEAM in any way so as to constitute unfair competition or deceptive, untrue, or misleading advertising;

b. Ordering Defendant to issue statements retracting its false and/or misleading and deceptive statements concerning the ANSR:BEAM by distributing such retractions, in a form approved by TRIA, to all recipients of Defendant's advertising containing said false and/or

misleading and deceptive statements and by posting such retractions on its website for at least six (6) months;

c. Ordering that all of Defendant's physical brochures, advertisements, press releases and promotional materials that contain unlawful statements concerning the ANSR:BEAM be recalled and destroyed;

2. That Defendant file with this Court and serve upon TRIA within fifteen (15) days after issuance of any injunction, a report in writing, under oath, setting forth in detail the manner and form in which Defendant has complied with the injunction.

3. That the Court award TRIA:

a. All damages sustained by reason of the wrongful acts complained of herein in an amount to be proven at trial;

b. Treble the amount of the actual damages suffered by TRIA pursuant to 15 U.S.C. § 1117;

c. Costs of this action;

d. Reasonable attorneys' fees, in that this is an exceptional case, within the meaning of 15 U.S.C. § 1117(a); and

e. Such other and further relief as the Court shall deem just.

On the Second and Third Claims for Relief

4. For preliminary and permanent injunctions:

a. Enjoining and restraining Defendant and its agents, servants and employees from publishing or publicly disseminating any statement, either directly or indirectly, concerning the nature, characteristics and qualities of the ANSR:BEAM in any way so as to constitute unfair competition or deceptive, untrue, or misleading advertising;

b. Ordering Defendant to issue statements retracting its false and/or misleading and deceptive statements concerning the ANSR:BEAM by distributing such retractions, in a form approved by TRIA, to all recipients of Defendant's advertising containing said false and/or misleading and deceptive statements and by posting such retractions on its website for at least six (6) months;

c. Pursuant to California Business and Professions Code § 17203, ordering that Defendant immediately cease and desist from making reference, either directly or indirectly, to the ANSR:BEAM in any way so as to constitute unfair competition or deceptive, untrue, or misleading advertising;

5. That Defendant file with this Court and serve upon TRIA within fifteen (15) days after issuance of any injunction, a report in writing, under oath, setting forth in detail the manner and form in which Defendant has complied with the injunction.

6. That the Court award TRIA:

a. Costs of this action;

b. Such other and further relief as the Court shall deem just.

JURY DEMAND

Plaintiff TRIA demands a jury trial for all claims as provided for in Federal Rule of Civil Procedure 38.

DATED: November 8, 2010

Respectfully submitted,

By: _____

Thad A. Davis
Joshua Van Hoven
ROPES & GRAY LLP
Attorneys for Plaintiff TRIA BEAUTY, INC.